



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 11 2002

Mr. John B. Howell  
General Counsel  
Bemis Manufacturing Company  
300 Mills Street  
Sheboygan Falls, Wisconsin 53085

Re: K020921

Trade/Device Name: No-Pokes Needle Safety Device (Recapper)  
Regulation Number: 880.5570  
Regulation Name: Hypodermic Single Lumen Needle  
Regulatory Class: II  
Product Code: FMI  
Dated: May 31, 2002  
Received: June 4, 2002

Dear Mr. Howell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

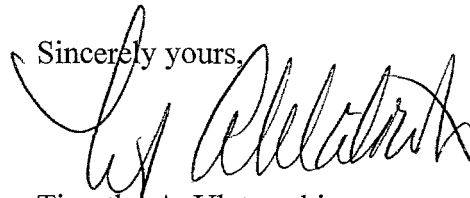
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration

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and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Timothy A. Ulatowski  
Director

Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(K) NUMBER: K020921

DEVICE NAME: NO-POKES™ Needle Safety Device

INDICATIONS FOR USE:

NO-POKES™ is a disposable needle recapping aid that helps prevent recapping injury by providing repository for the needle cap (other than the user's hand) in which to place the cap while using the syringe. This keeps the user's hand away from the needle during uncapping and recapping.

The cap of the capped needle is placed in the NO-POKES™. The "wax-like" substance in the NO-POKES™ holds the cap securely while the operator uses the needle. After the procedure, while the cap is secured in the NO-POKES™, the operator inserts the needle back into the cap without exposing his/her hand to the needle. The NO-POKES™ container has an adhesive on the base to hold it to the desired surface while in use.

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Concurrence of CERH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use \_\_\_\_\_  
(Optional Format 1-2-96)

Wade Hubbard for Pat Crisanti  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(K) Number K020921